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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/245,277	02/05/1999	PAUL P. WORLEY	10496/005001	4724

7590

05/05/2003

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/245,277

Applicant(s)

WORLEY ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 February 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-11 and 14-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 8-11 and 14-65 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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**DETAILED ACTION**

***Continued Prosecution Application***

1. The request filed on February 13, 2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/245,277 is acceptable and a CPA has been established. An action on the CPA follows.

***Response to Amendment***

2. Claims 1-7 have not been entered as requested in the amendment of Paper No. 23, filed on February 13, 2003 because claims 1-7 have been cancelled previously in the amendment of Paper No. 20, filed on October 09, 2002. The numbering of the newly presented claims 44-47 is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 44-47 have been renumbered as 62-65, respectively.

Claims 8-11 and 14-65 are pending in the instant application.

***Election/Restrictions***

3. Newly added claims 62-65 are directed to an invention that was not originally elected, see Paper No. 18. In view of M.P.E.P. 819, which states that "Where there is no indication in the CPA or FWC application that a change in election is desired, the examiner's first action should include a repetition of the restriction

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requirement made in the prior application to the extent it is still applicable in the CPA or FWC application and a statement that prosecution is being continued on the invention elected and prosecuted by applicant in the prior application. Examples of what is meant by the phrase "otherwise indicated by applicant" would be where the CPA or FWC is filed as (A) a divisional or (B) a continuation and includes an amendment filed prior to first action in the CPA or FWC adding claims to an invention not previously elected. In each of these examples the examiner should make a new restriction requirement in the first action",

restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 8-11, drawn to polypeptides, classified in class 530, subclass 350, for example.
- II. Claims 14-16, drawn to antibodies, classified in class 530, subclass 387.1, for example.
- III. Claims 17-25, drawn to cDNA libraries, classified in class 536, subclass 23.1, for example.
- IV. Claim 26, drawn to a method of obtaining immediate early gene nucleic acid, classified in class undetermined, subclass undetermined.
- V. Claims 27-30, drawn to a method of treating an animal by administering a nucleic acid, classified in class 514, subclass 44, for example.
- VI. Claim 31, drawn to a method of treating an animal by administering a polypeptide, classified in class 514, subclass 2, for example.

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- VII. Claim 32, drawn to a method of treating an animal by administering cells, classified in class 424, subclass 93.1, for example.
- VIII. Claims 33-34, drawn to a method of treating an animal by administering an antibody, classified in class 424, subclass 130.1, for example.
- IX. Claims 35-38, drawn to a method of identifying a compound involving a nucleic acid, classified in class undetermined, subclass undetermined, for example.
- X. Claims 39-43, drawn to a method of identifying a compound involving a polypeptide, classified in class undetermined, subclass undetermined, for example.
- XI. Claims 44-61, drawn to nucleic acid that encodes an amino acid sequence of SEQ ID NO: 32, and host cells, classified in class 435, subclass 69.1, for example.
- XII. Claims 62-65, drawn to a nucleic acid that encodes an amino acid sequence of SEQ ID NO: 27, classified in class 435, subclass 69.1, for example.

The inventions are distinct, each from the other because of the following reasons:

4. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group I and antibodies of Group II are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and entirely different process from the use for

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production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein.

2. Inventions I, III, XI and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the DNA may be used for the processes other than the production of the protein, such as nucleic acid hybridization assay.

3. Inventions II, III, XI and XII are unrelated also. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, antibodies of Group II can also be used in materially different methods, such as in various diagnostic (e.g. as a probe in immunoassays or immunochromatography), or therapeutic methods.

5. Inventions IV-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different methods that recite structurally and functionally distinct

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elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions.

6. Inventions I and (VI, X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group I could be used in an entirely different manner such as for the production of antibodies rather than in the methods of Groups (VI, XI).

7. Inventions (II, III, XI, XII) and (IV-X) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the antibodies, cDNA library and nucleic acids of Groups (II, III, XI, XII) are not required for the methods of Groups (IV-X).

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter and non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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9. The claims of Groups I-II and V-X are drawn to a multitude of polypeptides encoded by different nucleic acids (SEQ ID NO:1-57). This constitutes recitation of an implied, mis-joined Markush group that contains multiple, independent and distinct inventions. Each of the different nucleic acids/ polypeptides is independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121.

Upon election of one of Groups I-II and V-X, Applicant is additionally required to elect a single nucleic acid or polypeptide. This requirement is not to be construed as a requirement for an election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December



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28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.  
April 23, 2003

